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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/740,821	12/21/2000	Daniel C. Carter	P06896US00/BAS	6567

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STITES & HARBISON PLLC  
1199 NORTH FAIRFAX STREET  
SUITE 900  
ALEXANDRIA, VA 22314

EXAMINER
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LIU, SAMUEL W

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 11/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/740,821

Applicant(s)

CARTER, DANIEL C.

Examiner

Samuel W. Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 08 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 38-87 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 38-43 and 45-48 is/are rejected.
- 7) ☒ Claim(s) 44 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3/23/05 & 3/22/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

#### *Status of the claims*

Claims 38-48 are pending.

The amendment filed 8/8/05, which amends claims 38-44, has been entered. Also, applicants' request for extension (filed 8/8/05) of time for three months has been entered. Note that claims 1-37 were canceled by applicants' amendment filed 12/2/04.

Thus, the following Office action is applied to the pending claims 38-47. Please note that grounds of objection and/or rejection not explicitly restated and/or set forth below are withdrawn.

#### **IDS**

The references cited in the IDS filed 3/23/05 and the IDS filed 3/22/05 have been considered by Examiner.

#### ***Claim Rejections - 35 USC §102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 38-39, 43 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Mausner, J. (US Pat. No. 5254331) as is evidenced by the fact that ascorbyl palmitate has surfactant property shown by Palma et al. (*Eur. J. Pharmaceut. Sci.* (2002) 16, 37-43).

In the patent claim 1, Mausner teaches a skin cream composition comprising human serum albumin (see item (i)); and in the patent claim 2, Mausner teaches that said composition

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further comprises glyceryl arachidonate which has an inherent property of a skin cleansing agent when applied to skin. Also, in Table I, Mausner teaches that said skin cream comprises ascorbyl palmitate, which acts like surfactant (Palma et al. reference) wherein the surfactant, e.g., detergent is well-known cleansing agent absent factual indicia to the contrary (*note that soap is a surfactant, see the attachment*). The Mausner's teachings therefore anticipate instant claims 39, 38 and 45.

On column 7, line 3, Mausner teaches that the protein complex comprises about 28% serum protein (note that the patent claim 1 sets forth that the serum protein is human serum *albumin*). In the patent claim 1, item d, Mausner teaches that the protein complex comprises about 6.9% of said composition, i.e., the human serum albumin comprises 1.9% of said composition which is resulted from calculation:  $6.9\% \times 28\% = 1.9\%$ . The result 1.9% is equivalent to 1.9 g/100g, or approximately to 1.9 g per 100 ml of said skin *cream* composition, i.e., 19 mg/ml of the human serum albumin in said composition, which meets the limitation "1 to 250 mg/ml" of human serum albumin set forth in claim 43. Thus, the above Mausner's teaching anticipates instant claim 43.

Response to the rejection under USC 35 102(b)

The response filed 8/8/05 argues submits that the amended claims are directed to allowable subject matter. The applicants' argument is unpersuasive because the independent claims 39 and 45 as written are anticipated by the references stated above. It is of note that the current invention is directed to a composition comprising human serum albumin and a surfactant or detergent (soap is a surfactant or detergent) and that preambles, e.g., cleansing and

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hypoallergenic, have little patentable weight to the claimed composition, absent factual indicia to the contrary.

*The followings are the new ground of rejection.*

***Claim Rejections - 35 USC §103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 38-40, 43 and 45-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mausner, J. (US Pat. No. 5254331) taken with Carter et al. (US Pat. No. 6787636), further in view of the fact that ascorbyl palmitate has surfactant property shown by Palma et al. (*Eur. J. Pharmaceut. Sci.* (2002) 16, 37-43), and the fact that nickel metal is harmful for cosmetic preparation (Barczac, C. (1995) *The Hazards of Cosmetics*, pages 1-5).

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The Mausner et al. teachings are applied to instant claims 38-39, 43 and 45 have been set forth in the above statement.

Mausner et al. does not expressly teach that the human serum albumin is recombinantly produced.

Carter et al. teach that the recombinantly produced human serum albumin (rHSA) can be used safely and effectively as a cosmetic component (see column 3, lines 51-58), as applied to instant claims 40 and 46.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the cleansing composition comprising rHSA which substitutes for naturally-occurring HAS and a surfactant which acts like soap. One skilled in the art would have been motivated to do this because the Carter's rHSA comprising structural modification at metal binding site VI-region is so generated in order to reduce or eliminate unwanted binding of trace metals (free of trace metals), e.g., nickel and copper (see column 4, lines 14-45). It has been known that the nickel compound can cause skin rash when used in cosmetics (see the attachment "*The Hazards of Cosmetics*", page 4). Hence, the skilled artisan would have substituted rHSA for natural serum albumin for use in formulation of the said cleansing composition.

Therefore, the claimed invention was *prima facie* obvious to make and use the invention at the time it was made.

Claims 39-43 and 45-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (*Biochem. Biophys. Acta* (2000, June) 1479, 321-331) taken with Carter et al. (US Pat. No. 6787636), and further in view of the fact that nickel metal is harmful for cosmetic

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preparation (Barczac, C. (1995) *The Hazards of Cosmetics*, pages 1-5); wherein sodium laureth sulfate taught by Nielson et al. has inherent property of acting as detergent cleansing agent shown by Paula Begoun-the cosmetics cop (2005) *Cosmetic ingredient dictionary*, “sodium laureth sulfate” section, page 2).

In “*Materials and methods*” section, Nielsen et al. teach a composition comprising a bovine serum albumin (BSA), and a detergent sodium laureth sulfate, wherein said detergent is dissolved in buffer solution comprising 20 mM Tris, 100 mM NaCl at pH7.0. The composition is qualified for a cleansing composition since the sodium laureth sulfate is a detergent cleansing agent (see page 2 of the Paula Begoun-the cosmetics cop reference). The Nielsen et al. teachings are applied to instant claims 39, 41, 45 and 47. It is of note that the detergent cleansing agent is a kind of soap.

Nielsen et al. teach that the said albumin protein of 100  $\mu$ M which is equivalent to 6.7 mg/ml (in view of BSA molecular weight is about 67,000 daltons) is dissolved in the solution comprising 4mM sodium laureth sulfate (i.e.,  $\sim$  1.15 mg/ml sodium laureth sulfate in light of molecular weight of sodium laureth sulfate is about 288 daltons), which is applied to instant claims 42-43.

Please note that “cleansing agent” has been given itself patentable weight in claim 37 and that the current claim language as written is broadly drawn to encompassing any type of detergent cleansing agent. Also, note that the preambles “*for skin or hair*” after “composition”, and “cleansing” before “composition” (claim 39, 38 and 40-44), and “hypoallergenic cleaning” before “composition” (claims 45-48) are considered to have little patentable weight. This is because structural feature is inherent property of a biomolecule; the above-stated functional

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preambles “cleansing” and “hypoallergenic cleansing” would not alter property/components of the claimed composition. It is of note that products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada* 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

The above-mentioned Nielsen et al. teachings, however, does not expressly teach that the serum albumin is recombinantly produced human serum albumin.

Carter et al. teach that the recombinantly produced human serum albumin (rHSA) can be used safely and effectively as a cosmetic component (see column 3, lines 51-58), as applied to instant claims 39-43 and 45-48.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a cleansing composition comprising rHSA which substitutes for natural BSA and the said sodium laureth sulfate – a detergent cleansing agent, which acts like soap. One skilled in the art would have been motivated to do this because the Carter’s rHSA comprising structural alteration at metal binding site VI-region which is generated so as to reduce or eliminate unwanted binding of trace metals (free of trace metals), e.g., nickel and copper (see column 4, lines 14-45). It has been known that the nickel compound can cause skin rash when used in cosmetics (see the attachment “*The Hazards of Cosmetics*”, page 4). Hence, the skilled artisan would have substituted the said rHSA for natural serum albumin (BSA) for use in formulation of the said cleansing composition.



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Therefore, the claimed invention was *prima facie* obvious to make and use the invention at the time it was made.

NOTE: Claim 44 is objected to as being dependent upon a rejected base claim 39, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

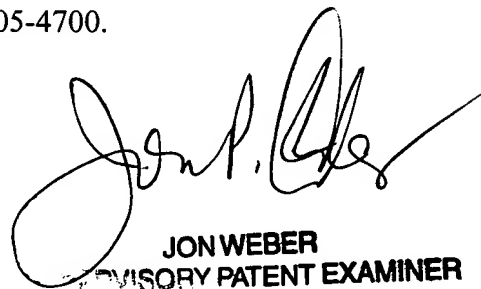
***Conclusion***

No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:30 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weber, Jon, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.



Samuel Wei Liu, Ph.D.  
October 19, 2005



JON WEBER  
ADVISORY PATENT EXAMINER